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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

TATE, CHRISTOPHER ROBIN

ART UNIT PAPER NUMBER

1654

DATE MAILED: 01/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,558

Applicant(s)

SPIESS, STEFAN

Examiner

Christopher R. Tate

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15,17-21 and 23-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 17-21, and 23-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 6, 2004 has been entered.

Claims 15, 17-21, and 23-42 (submitted in the amendment filed July 2, 2004) are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-34 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating and/or reducing the risk of migraine headaches in a subject in need thereof, does not reasonably provide enablement for preventing such migraine headaches. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

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Applicants have reasonably demonstrated/disclosed that the claimed compound is useful as a therapeutic agent for treating migraines and/or reducing the risk thereof. However, the claims also encompass using the claimed herbal preparation to prevent migraines which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented with current therapies (other than certain vaccination regimes) - including preventing such disorders as migraines (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or utilize the instantly claimed herbal preparation to prevent migraine headaches as claimed.

It is suggested that independent claim 27 be amended by replacing the phrase "the treatment or prevention of migraine in a subject in need of such treatment or prevention" (lines 1-2) with the phrase --treating or reducing the risk of a migraine in a subject in need thereof-- to overcome this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 15, 17-21, and 23-26, 35-37, 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 15 and 42 are rendered vague and indefinite because they fail to recite operative amounts of the claimed herbal ingredients. Therefore, it is unclear if the herbal ingredients is/are active agents within the composition, if it/they are merely some type of inert agents, and/or if it/they are present in very small amounts representing perhaps a contaminant or residue. The two main herbal ingredients (i.e., *Tanacetum parthenium* and *Vitex agnus-castus* or *Tanacetum parthenium* and *Cimicifuga racemosa*) are deemed to be essential bioactive elements of the invention and, as such, they should be clearly defined (at least functionally) in the claim language itself. Accordingly, it is suggested that the phrase --effective amounts of-- be inserted after the word "comprising" (line 2 of both claims) or, alternatively, that the limitations recited in claims 23-25 be appropriately incorporated into claims 15 and 42, to clarify this ambiguity.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 15, 17-21, and 23-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyandt et al. (Drug Topics, June 98 - PROMT Abstract), Castleman (The Healing Herbs, 1991), Marles et al. (J. Nat. Prod., 1992), the PDR for Herbal Medicines (published Spring 1998), and the admitted state of the art, in view of Thys-Jacobs (US 5,443,850).

Wyandt et al. disclose that feverfew (aka *Tanacetum parthenium*) has a long history of use in traditional and folk medicine as a treatment for menstrual irregularities as well as, more recently, as a treatment for migraine headaches (see abstract).

Castleman teaches that ginger (*Zingiber officinale*) is well known in the art to have traditional use in women's health for treating menstrual cramps and gynecological problems, as well as a digestive aid in relieving gastrointestinal distress (see, e.g., pages 187-188). Marles teaches that ginger is also well known in the art to have traditional use in treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047).

The PDR for Herbal Medicines reference teaches that *Cimicifuga racemosa* (black cohosh) and *Vitex agnus-castus* (chaste tree) are well known in the art to be useful in treating menstrual/premenstrual disorders (see heading *Indications and Usage* for both plants). In addition, as readily admitted by applicant, it is well known in the herbal art that *Tanacetum parthenium* is useful for treating and preventing migraines (see, e.g., page 4, first full paragraph of the instant specification), and that *Vitex agnus-castus* and *Cimicifuga racemosa* are both useful in treating premenstrual disorders (see, e.g., pages 5-6 of the instant specification). Further, as readily admitted by applicant, most migraine sufferers are women and they are most likely to suffer a migraine during their menstrual periods (see, e.g., the last six lines on page 3 of the instant specification). Also, as disclosed by Thys-Jacobs, seventy percent of women who

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suffer migraines report a significant proportion of attacks during their premenstrual period (see, e.g., col 1, lines 22-49).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known beneficial uses since each is well known in the art for such uses (i.e., to treat and/or prevent migraines as well as menstrual/premenstrual disorders, especially since women are the predominant sufferers of migraines and suffer migraines most often during their menstrual/premenstrual periods) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980); *In re Sussman*, 1943 C.D. 518; *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (i.e., specific proportions and/or amount ranges of both of the two essential active herbal ingredients - *Tanacetum parthenium* and *Vitex agnus-castus* or *Tanacetum parthenium* and *Cimicifuga racemosa*. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore ipso facto unpatentable.

Accordingly, the instantly claimed herbal combination (and method of use), in the range of proportions and/or amounts where no unexpected results are observed, would have been

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obvious to one of ordinary skill having the above cited teachings before him/her. The adjustment of particular conventional working conditions (e.g., determining a result-effective amount of one or more of the claimed herbal ingredients for use in either treating/preventing a migraine or menstrual/premenstrual disorders) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. With respect to the product claims, please also note that the intended use of the claimed herbal preparation (e.g., treating menstrual/premenstrual disorders, vs. treating/preventing migraines - as instantly claimed) does not patentably distinguish the preparation per se, since such undisclosed use is intrinsic to the herbal preparation reasonably taught by the above cited teachings (see, e.g., MPEP 2112).

From the cited teachings, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicants' arguments as they pertain to the USC 103 rejection above (including the data presented in the July 2, 2004 Declaration of Stefan Speiss) have been carefully considered but are not deemed to be persuasive of error.

Applicants argue the following:

- That Wyandt only teaches vague generalities about parthenium and ginger. However, this reference was relied upon because it does in fact beneficially disclose that feverfew (aka *Tanacetum parthenium*) has a long history of use in traditional and folk medicine as a treatment

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for menstrual irregularities as well as, more recently, as a treatment for migraine headaches (see abstract), as discussed above.

- That Castleman appears to be a collection of the history and folklore regarding ginger. The examiner agrees that this reference was why this reference was relied upon - i.e., because it does, in fact, teach that ginger (*Zingiber officinale*) is well known in the art to have traditional use in women's health for treating menstrual cramps and gynecological problems, as well as a digestive aid in relieving gastrointestinal distress (see, e.g., pages 187-188).

- That Marles is mainly concerned with a bioassay for detecting various sources of parthenium and is at best cumulative. However, this reference was relied upon because it does, in fact, beneficially teach that ginger is also well known in the art to have traditional use in treating and preventing migraines (see, e.g., paragraph bridging pages 1046-1047), as discussed above.

- That the PDR for Herbal medicines does not support the obviousness rejection because the prior believed effects of the herb *Cimicifuga* are not supported by research results and that this reference only teaches the use of *Cimicifuga* for climacteric complaints or ailments and there is no mention of treatment of migraines. However, this reference was relied upon because it does, in fact, beneficially teach that *Cimicifuga racemosa* (black cohosh) and *Vitex agnus-castus* (chaste tree) are well known in the art to be useful in treating menstrual/premenstrual disorders (see heading *Indications and Usage* for both plants).

- That there is no prior art admission in the present specification regarding using *Vitex agnus-castus* and *Cimicifuga racemosa* for treatment of migraines. However, as discussed above, the specification does admit that *Vitex agnus-castus* and *Cimicifuga racemosa* are both well known to be useful in treating premenstrual disorders (see, e.g., pages 5-6 of the instant specification).

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- That Thys-Jacobs (US 5,443,850) is cited only for its review of statistical information and, further, is non-analogous art or teaches away from the now claimed invention. However, this reference was relied upon because it does, in fact, beneficially teach that seventy percent of women who suffer migraines report a significant proportion of attacks during their premenstrual period (see, e.g., col 1, lines 22-49).

As noted in the previous Office action, Applicants have argued and discussed references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which make up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the references. Applicants further argues that although the Examiner previously stated Applicants have discussed the various cited references individually without addressing the combined teachings, with all due respect, the examiner has cited the references individually and only given generalized conclusions of the results of the combined references. However, the USC 103 rejection is deemed proper and clear for the reasons set forth above with respect to the beneficial cited teachings therein.

Further, please note that based upon the teachings of the cited art as a whole (including, e.g., for treating various conditions such as menstrual disorders, irregularities, cramps, and/or potential migraines commonly associated therewith) the administration of two or more of the claimed plant components for their known benefit(s) - as discussed *supra* - would intrinsically prevent migraines from occurring.

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It is reemphasized that Applicants invention is predicated on an unexpected result (such as the unexpected beneficial results reasonably demonstrated in the July 2, 2004 Declaration by Stefan Spiess) which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients (i.e., operative amounts and/or ratios of each of the two or more active ingredients therein, not just one - as instantly claimed, e.g., in claims 23-25 and 30-32, 35, 36, 38, 39, and 41). Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him, with respect to each of the U.S.C. 103 rejections set forth above.

To hasten prosecution, it is suggested that claims 23-25 be appropriately incorporated into independent claims 15 and 42, and that claims 30-33 be appropriately incorporated into independent claim 27, so as to adequately define and distinguish the invention with respect to the amount ranges of the claimed herbal ingredients that provide for unexpected (synergistic) beneficial effects (such as those discussed in the July 2, 2004 Declaration).

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Christopher R. Tate
Primary Examiner
Art Unit 1654